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2007

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No. 06-

IN THE

Supreme Court of the United States

MOSHE MILSTEIN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

JACOB LAUFER
Attorney for Petitioner
65 Broadway
New York, NY 10006
(212) 422-8500

QUESTIONS PRESENTED

1. Does the Fifth Amendment's Grand Jury Clause permit the Government to obtain a conspiracy conviction under 18 U.S.C. §371 without proving an overt act charged in the indictment?

2. May the Government secure a conviction under 18 U.S.C.§371 by proof of an uncharged overt act founded in a theory that both constructively amended the indictment, and was time-barred as a matter of law?

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OPINIONS BELOW

The decision of the United States Court of Appeals for the Second Circuit affirming the final judgment entered March 27, 2007, is reported at 481 F.3d 132 (2d Cir. 2007). It may be found in Appendix "A." The earlier opinion of the United States Court of Appeals for the Second Circuit which resulted in a partial reversal and remand is reported at 401 F.3d 53 (2d Cir.2005) and may be found in Appendix "B." An unreported decision of the district court, 2000 WL 516784 (E.D.N.Y. March 03, 2000), which does not bear upon the issues raised in this petition, may be found in Appendix "C."

JURISDICTION

The decision of the United States Court of Appeals for the Second Circuit was entered on March 26, 2007. No petition for rehearing was filed. This Court's jurisdiction is invoked pursuant to 28 U.S.C. §1254(1).

CONSTITUTIONAL PROVISIONS AND STATUTES

United States Constitution, Amendment V. No person shall be held to answer for a ... crime ... unless on a presentment or indictment of a Grand Jury.

United States Constitution, Amendment VI. In all criminal prosecutions, the accused shall enjoy the right ... to be informed of the nature and cause of the accusation ...

18 U.S.C. §371: If two or more persons conspire either to commit any offense against the United States ... and one or more persons do any act to effect the object of the conspiracy, each shall be fined ... or imprisoned not more than five years, or both ...

18 U.S.C. §3282: Except as otherwise expressly provided by law, no person shall be prosecuted, fined, or punished for any offense, not capital, unless the indictment or the information is instituted within five years next after such offense shall have been committed.

STATEMENT OF THE CASE

Petitioner, Moshe Milstein, was convicted of regulatory and trademark offenses, by taking advantage of the price discrepancy between the United States and European markets for pharmaceuticals which sold in this country for a significantly higher price than abroad. The Government charged that Milstein and others purchased large quantities of such drugs in foreign markets, repackaged them with counterfeit packaging so as to pass them off as their domestic counterparts, and sold them to New York pharmacists and others.[1]

The indictment alleged 30 overt acts, 18 of which

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1. The indictment returned charged Milstein with fraudulently distributing misbranded drugs (21 U.S.C. §§331 [a][2]) (count three); distributing wholesale prescription drugs without a required state license (21 U.S.C. §§331[t], 333[b][1], and 353[e][2][A]) (count four); distributing prescription drugs in violation of trademark laws (18 U.S.C. §2320[a]) (count two); distributing wholesale prescription drugs without providing a history of transactions (21 U.S.C. §§331[t], 333[a][2], 353[e][1][A]) (count five), and conspiring to commit the offenses specified in counts two, three and four (18 U.S.C. §371) (count one).

charged conduct outside the five-year limitations period, *i.e.*, before September 17, 1993. Milstein's last charged sale occurred on August 9, 1993, and his last charged conduct of any sort occurred in September 17, 1993, one day short of five years before the return of the indictment, when he allegedly "caused" two checks (dated September 9, 1993) totaling approximately $47,000 and representing the proceeds of his last sales to be deposited at a Zurich branch of an Israeli bank in the name of "Heldra." These two overt acts were alleged to have been committed on the dates the checks were deposited. The only other timely overt acts alleged three deliveries to a pharmacy by a co-defendant.

In opposition to Milstein's pre-trial motions, filed about two months before trial was to begin, the Government claimed for the first time, that recently performed testing revealed that certain samples seized from a co-conspirator six years earlier were contaminated, which the Government counted was relevant to the misbranding charge in count three. The court refused to exclude the "contamination" evidence, but granted a five month adjournment of the trial.

Shortly before the trial was to begin, the Government

obtained a superseding indictment charging Milstein and his wife with a tax offense, which the court severed.[2] Otherwise, the indictment was identical to the original. Although the contamination evidence was put before the Grand Jury, the indictment omitted any reference to "contamination" as a theory of the misbranding charge in count three. Rather, it alleged in count three that Milstein and others had sold "re-packaged drugs as if they were the original product from the licensed manufacturers, thus distributing misbranded drugs."

Count four of the indictment failed to allege the jurisdictional interstate commerce element under 21 U.S.C. §353[e][2][A]. Once jeopardy attached, Milstein made a motion for a judgment of acquittal on that count, but the court denied the motion after permitting the Government to obtain a mid-trial superseding indictment alleging the missing element.

Milstein urged that admission of "contamination" evidence under count three would violate his Fifth and Sixth

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2. Milstein's wife, Ethel Milstein, was indicted along with him, on what the district court noted was "virtually no evidence." She was acquitted on a Rule 29 motion.

Amendment rights, as a constructive amendment of the indictment, as "the grand jury could not have contemplated the Government's new contamination theory of misbranding because the Government did not even start the testing that ultimately produced the supposed evidence of contamination until the summer of 1999."

The district court rejected the argument and received the evidence of contamination. It instructed the jury that it could convict on count three, the misbranding count, either on a false origin theory or on a contamination theory. Milstein was convicted on all counts, and then entered a conditional guilty plea to the tax count. He was sentenced to a four year prison term and restitution of approximately $3.5 Million.

On appeal, the United States Court of Appeals for the Second Circuit held that the contamination theory constituted a constructive amendment of the indictment because it did not "place Milstein on notice that the Government would . . . attempt to prove that the drugs were not sterile." United States v. Milstein, 401 F.3d 53, 65 (2d Cir. 2005) (*per curiam*). The Court rejected Milstein's contention that

reversal of count three would require reversal of all counts, specifically concluding that the contamination evidence was admissible in connection with count one because "even if the jury convicted Milstein on the conspiracy count based on evidence of an overt act not specified in the indictment (*e.g.*, an overt act involving drugs deemed misbranded because they are dangerous to health even when used as their labeling directed), the jury's reliance on that evidence would not require vacatur of Milstein's conspiracy conviction absent some indication that Milstein suffered prejudice as a result." Id., 401 F.3d at 70-71.

The case was remanded for retrial of count three, at the Government's option, and, in any event, for re-sentencing. The Government chose not to retry count three, and the district court resentenced Milstein to a lesser term of 20 months imprisonment and the same restitution.

Following entry of judgment, Milstein appealed again, contending that the conclusion that count three, the misbranding count, had been constructively amended compelled dismissal of count one, which charged among other things, a conspiracy to commit the misbranding count

set out in count three, and that the district court erred in allowing restitution for lost profits.

The Court of Appeals rejected both arguments. It summarily reaffirmed its prior conclusion that the jury, as charged, was not presented with a constructive amendment of count one, and would have considered the contamination evidence, as far as the conspiracy count was concerned, as evidence of overt acts taken in furtherance of the conspiracy, even though they were not set forth in the indictment. *United States v. Milstein*, 481 F.3d 132, 134 n.1 (2nd Cir. 2007).

REASONS FOR GRANTING THE WRIT

I

This petition raises an issue that is germane to many, if not most, federal criminal prosecutions: Is an overt act an element of a conspiracy charge under 18 U.S.C. § 371?[3]

In the setting of the common law principle that the

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3. The issue raised affects other statutes as well. "Congress has included an express overt-act requirement in at least 22 other current conspiracy statutes . . ." *Whitfield v. United States*, 543 U.S. 209, 216 (2005).

only act required for a conspiracy was the act of entering into an agreement, *Hogan v. O'Neill*, 255 U.S. 52, 55 (1920), and the increasing enactment of conspiracy crimes that do not require an overt act, the overt act requirement in 18 U.S.C. § 371 prosecutions has increasingly been treated by the lower courts as a vestigial anachronism.

Academically, the text of the statute, and the pattern jury instructions suggest, indeed state, that the overt act component of the crime is an element of the crime. The lower courts, while acknowledging this, do not treat it as an element of the crime.

If an overt act is indeed an element of the crime, then the protection afforded conspiracy defendants by the Constitution's Grand Jury Clause has been, piecemeal, eroded by lower court decisions. The once rosy apple of this Constitutional protection – for conspiracy defendants – has suffered numerous bites, each small and some barely perceptible. In this case, even its core has been eaten.

The general federal conspiracy statute, 18 U.S.C. § 371, is straightforward. It requires that two or more persons conspire to commit any federal crime, and that "one or more

of such persons do any act to effect the object of the conspiracy." A commonly used pattern jury instruction, Sand, *Modern Federal Jury Instructions*, Instruction 19-7, provides, forthrightly: "[I]t is not required that all of the overt acts alleged in the indictment be proven. . . . [T]he overt act need not have been committed at precisely the time alleged in the indictment. It is sufficient if you are convinced beyond a reasonable doubt, that it occurred at or about the time and place stated." *See also*, Sixth Circuit Pattern Jury Instructions ("The third element that the government must prove is that a member of the conspiracy did one of the overt acts described in the indictment for the purpose of advancing or helping the conspiracy.")

"Conviction under the general conspiracy statute requires more than mere agreement, namely, the commission of an overt act." *Blumenthal v. United States*, 332 U.S. 539, 560 n.18 (1947).[4] Yet, there is a vacuum in this Court's

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4. Congress, in the general conspiracy statute, intended the overt act requirement to play an important role because overt acts are the only external manifestation of a crime otherwise "predominantly mental in composition." *Krulewitch v. United States*,

teaching that sets the overt act requirement on an unsteady foundation. Over sixty years ago, the Court left undecided "whether we regard the overt act as a part of the crime which the statute defines and makes punishable, . . . or as something apart from it, either an indispensable mode of corroborating the existence of the conspiracy or a device for affording a locus poenitentiae . . . " *Braverman v. United States*, 317 U.S. 49, 53 (1942) (citations omitted)[5]

The Court has not in the intervening 65 years

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336 U.S. 440, 447-48 (1949) (Jackson, J., concurring). Overt acts show that "the conspiracy is at work" *Yates v. United States*, 354 U.S. 298, 334 (1957).

5. In *Hyde v. United States*, 225 U.S. 347, 369 (1912), the Court construed the overt act requirement as an element of the crime of conspiracy for venue purposes. Justice Holmes dissented vigorously, arguing that the overt act was "no more a part of the crime than it was at common law," but was "simply evidence that the conspiracy has passed beyond words and is on foot when the act is done." 225 U.S. at 388. He agreed with the view expressed in *United States v. Britton,* 108 U.S. 199, 204 (1883), that the statutory requirement of an act did not add another element to the crime, but "merely afford-[ed] a locus penitentiae."

answered this open question. In *United States v. Shabani*, 513 U.S. 10, 14 (1994), the Court broadly intimated that commission of an overt act is an essential element of a §371 conspiracy. (overt act is "explicit requirement" and "additional element" of 18 U.S.C. §371, but not of 21 U.S.C. §846).[6]

Thereafter, in *Whitfield v. United States*, 543 U.S. 209 (2005), the Court made plain the construction to be

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6. The overt act requirement has appeared in the federal conspiracy statute since §371's earliest predecessor was enacted in 1867. R.S. §5440, 14 Stat. 484 (1867). The framers of the Constitution included an overt act requirement in the Treason Clause. U.S. Const. art. III, §3 ("No Person shall be convicted of Treason unless on the Testimony of two Witnesses to the same overt Act"). The 39th Congress, which enacted §371's predecessor soon after the Civil War ended, likely had the Treason Clause in mind, and intended the overt act element of the statute to be accorded similar importance. *See Cramer v. United States*, 320 U.S. 1 (1945); *United States v. Burr*, 25 F. Cas. 55, 170 (1807) (Marshall, C.J.) ("If it be necessary to specify the charge in the indictment, it would seem to follow, irresistibly, that the charge must be proved as laid. All the authorities which require an overt act, require also that this overt act should be proved. . . . ").

given conspiracy statutes: "*Shabani* distilled the governing rule for conspiracy statutes as follows: "'*Nash* [*v. United States*, 229 U.S. 373 (1913)] and *Singer [v. United States*, 323 U.S. 338 (1945)] give Congress a formulary: by choosing a text modeled on § 371, it gets an overt-act requirement; by choosing a text modeled on the Sherman Act, 15 U.S.C. § 1 [which, like 21 U.S.C. § 846, omits any express overt-act requirement], it dispenses with such a requirement.'" 513 U.S., at 14, 115 S.Ct. 382." *Whitfield*, 543 U.S. at 214.

But, following the teaching of *Whitfield* and *Shabani* that certain conspiracy prosecutions require proof of an overt act, the question remains: Is an overt act a true element of a conspiracy prosecution? In the absence of definitive guidance from this Court, the overt act requirement has receded in judicial regard; even in conventional § 371 conspiracy cases, this requirement has been increasingly honored in the breach.

The status of the overt act requirement directly implicates Constitutional concerns. The Fifth Amendment requires that a defendant be convicted on facts found by a

grand jury, U.S. Const. amend. V. In *Russell v. United States*, 369 U.S. 749, 770 (1962), the Court held that a defendant cannot be convicted on the basis of facts that may not have been specifically presented to, and found by, a grand jury. In particular, the Court noted that "[t]o allow the prosecutor, or the court, to make a subsequent guess as to what was in the minds of the grand jury at the time they returned the indictment would deprive the defendant of a basic protection which the guaranty of the intervention of a grand jury was designed to secure." *See also, Stirone v. United States*, 361 U.S. 212, 217 (1960)(the Grand Jury Clause requires that a defendant may not be tried "on charges that are not made in the indictment against him.")

When the trial evidence or the jury instructions operate to "broaden[] the possible bases for conviction from that which appeared in the indictment," the indictment has been constructively amended. *United States v. Miller*, 471 U.S. 130, 138 (1985). A constructive amendment of the indictment is a *per se* violation of the Fifth Amendment, requiring reversal without a showing of prejudice. *See Stirone*, 361 U.S. at 217 ("deprivation of such a basic right

is far too serious to be treated as nothing more than a variance and then dismissed as harmless error").

In our case, there is no doubt that the petitioner was convicted of conspiracy based upon proof of an overt act that was not charged by the grand jury. Having reversed the petitioner's misbranding conviction under one count of the indictment on constructive amendment grounds, 401 F.3d at 64-66, *citing Stirone v. United States*, the court inconsistently upheld his conspiracy conviction, founded upon proof of that same conduct. The court employed a variance, harmless error analysis, *i.e.*, "even if the jury convicted Milstein on the conspiracy count based on evidence of an overt act not specified in the indictment . . . the jury's reliance on that evidence would not require vacatur of Milstein's conspiracy conviction absent some indication that Milstein suffered prejudice as a result." 401 F.3rd at 70-71. In an earlier understatement, the court noted that "the cases dealing with claims of constructive amendment sometimes appear to reach divergent results." 401 F.3rd at 65 (citations omitted). *See also, United States v. Rigas*, --- F.3d ----, 2007 WL 1518619 *14 (2nd Cir. May 24, 2007)(same)

Fundamentally, must the Government prove at least one of the overt acts alleged in an indictment? Is proof of a "substantially similar" overt act sufficient? Is it enough that Government prove any overt act at all, so long as the defendant is not prejudiced thereby? The answers turns on resolution of the question that *Braverman* left open.

"In order for an accusation of a crime (whether by indictment or some other form) to be proper under the common law, and thus proper under the codification of the common-law rights in the Fifth and Sixth Amendments, it must allege all elements of that crime; likewise, in order for a jury trial of a crime to be proper, all elements of the crime must be proved to the jury (and, under *[In re Winship,* [397 U.S. 358 (1970)] proved beyond a reasonable doubt)." *Apprendi v. New Jersey*, 530 U.S. 466, 499 (2000) (Thomas, joined by Scalia, JJ., concurring) (citations omitted)

If the overt act requirement is indeed an element of the crime, then an indictment must allege the charging overt acts, as essential elements of the offense charged. "An indictment must set forth each element of the crime that it charges." *See Almendarez-Torres v. United States,* 523 U.S.

224, 228 (1998). An indictment must "fully, directly, and *expressly,* without any uncertainty or ambiguity, set forth all the elements necessary to constitute the offence intended to be punished." *United States v. Carll*, 105 U.S. 611, 612 (1881) (emphasis added); *see United States v. Resendiz-Ponce*, 127 S.Ct. 782, 790 (2007)(Scalia, J., dissenting).

While it is "a long-established rule of the criminal law that an indictment need not specify which overt act, among several named, was the means by which a crime was committed." *Schad v. Arizona*, 501 U.S. 624, 631 (1991), the teaching of *Russell* and *Stirone* dictates that at least one of the alleged overt acts must be proved, or at minimum the proven overt act must be sufficiently similar to the alleged overt acts, in order that there not be a constructive amendment of the indictment.

If, on the other hand, the overt act requirement is not an element of the crime, then the teaching of *United States v. Miller,* 471 U.S. 130 (1985) obtains, and as a part of the indictment unnecessary to and independent of the allegations of the offense charged, the alleged overt acts may be treated as "useless averment[s]" that "may be ignored." *Id.*, 471 U.S.

at 136, quoting *Ford v. United States*, 273 U.S. 593 (1927).

The lower courts have tended, progressively, toward abnegation of the overt act requirement. By way of example, the court in *Fredericks v. United States*, 292 F. 856, 857 (9th Cir. 1923), held, in reversing a conviction, that "[w]here more than one overt act is charged, the prosecution need not prove all of them; but it is fundamental that some overt act alleged must be proved. But under the charge the jury might well have believed that, if they found that defendants had done any overt act to effect the object of the conspiracy, conviction should follow, even though the specific act charged was not proved." *Fredericks* was thereafter reexamined by the Ninth Circuit in *Brulay v. United States*, 383 F.2d 345 (9th Cir.), *cert. denied*, 389 U.S. 986 (1967), which concluded that *Fredericks* was no longer viable in light of Fed.R.Crim.P. 52(a). The court held that a variance between the single overt act alleged in an indictment and the one proved at trial constituted harmless error.

In our own case, the court of appeals held that it is a "well-established rule of this and other circuits that the overt act element of a conspiracy charge may be satisfied by an

overt act that is not specified in the indictment, at least so long [as] there is no prejudice to the defendant." *United States v. Milstein*, 401 F.3d 53, 70 (2nd Cir. 2005), *citing United States v. Frank*, 156 F.3d 332, 337 (2nd Cir. 1998). *Frank*, in turn, supported its holding with decisions of the First, Second, Third, Fifth, Seventh and Ninth Circuits. 156 F.3d at 337-38. To this list may be added the Fourth Circuit, *United States v. Molovinsky*, 688 F.2d 243, 246 n.5 (4th Cir. 1982), Eighth Circuit, *United States v. Lewis*, 759 F.2d 1316 (8th Cir.), *cert. denied*, 474 U.S. 994 (1985), and the Tenth Circuit, *United States v. Stoner*, 98 F.3d 527 (10th Cir. 1996).

These decisions reason that the change in overt acts from indictment to trial constitutes a simple variance. *See generally Dunn v. United States*, 442 U.S. 100, 105 (1979) (defining a variance as "aris[ing] when the evidence adduced at trial establishes facts different from those alleged in an indictment."). According to these decisions, including that in our case, such a simple variance does not warrant the reversal of a conviction so long as the variance "d[id] not affect [the defendant's] substantial rights," Fed.R.Crim.P.

52(a). But, this analysis pays no respect to the fact that the petitioner was convicted on a legally inadequate, unconstitutional ground. *Griffin v. United States*, 502 U.S. 46(1991); *Yates v. United States,* 354 U.S. 298 (1957); *Stromberg v. California*, 283 U.S. 359 (1931).

The slippage in judicial discipline regarding the overt act requirement becomes clear when one examines the actual jury instruction that was approved in *United States v. Frank, supra.* That jury instruction required the jury to "agree on at least one overt act charged or substantially the same as one explicitly charged." 156 F.3d at 337. In affirming, the court broadly intimated that this jury instruction was more generous to the defendant than warranted, and held that any overt act at all is sufficient, "at least so long as there is no prejudice to the defendant." 156 F.3d at 337 (citations omitted).

In a very recent decision, the Second Circuit has strayed yet further from Constitutional doctrine. In *United States v. Rigas*, --- F.3d ----, 2007 WL 1518619 *15 (2nd Cir. May 24, 2007), the court virtually detoured around this Court's teaching regarding the bar against constructive

amendment of indictments. In rejecting a claim that the evidence at trial had constructively amended the indictment, the court relied upon *United States v. Resendiz-Ponce*, 127 S.Ct. 782, 788 (2007), and concluded that the Grand Jury Clause was sufficiently satisfied if an indictment contains the elements of the charged offense, fairly informing the defendant of the charge, and that it adequately protects the defendant from multiple prosecutions. But, "these 'notice' related concerns" are only "among" the several concerns of the Grand Jury Clause. *See United States v. Miller, supra*, 471 U.S. at 135. And *Resendiz-Ponce* did not deal at all with the matter of constructive amendments; it addressed whether or not an indictment had sufficiently alleged all elements of the charged crime.

If an overt act is an essential element of a §371 conspiracy, it is impossible to harmonize the Constitutionally-based principle that the government must prove the elements of the crime as charged in the indictment with the drift by the lower courts away from the requirement that the government prove at least one of the alleged overt acts, to a harmless error analysis under Rule 52(a),

Fed.R.Crim.P.

If the overt act requirement is not an element of a § 371 prosecution, then this teaching should ideally come from Congress. Absent legislative revision of this statute, it should be applied as enacted. At minimum, the abnegation of the overt act requirement, if appropriate, should rest upon the *imprimatur* of the Court.

In short, the Second Circuit has decided an important question of conspiracy law affecting the general conspiracy statute, and 22 other conspiracy statutes, that has not been, but should be, settled by this Court. U.S. Sup. Ct. Rule 10(c). At the same time, the Second Circuit has disregarded this Court's constructive amendment jurisprudence, and has thereby "decided an important federal question in a way that conflicts with relevant decisions of this Court." *Id.*

Respectfully, it would be appropriate for this Court to examine this ubiquitously recurring issue.

II

Ancillary to the first point raised above, is the significance of the overt act requirement in its relation to the

statute of limitations.

Under Second Circuit rulings,"the statute of limitations may be satisfied by proof of an overt act not explicitly listed in the indictment." *United States v. Frank*, 156 F.3d 332, 337 (2d Cir. 1998) (*per curiam*). The Third Circuit agrees with Second Circuit. *See, United States v. Schurr*, 794 F.2d 903, 907 n.4 (3d Cir. 1986)

The Fourth, Fifth, Eighth and Eleventh Circuits squarely reject this holding. *See, United States v. Davis*, 533 F.2d 921, 929 (5th Cir. 1976); *United States v. Head*, 641 F.2d 174, 178 n.5 (4th Cir. 1981), *cert. denied*, 462 U.S. 1132 (1983); *United States v. Dynalectric Co.*, 859 F.2d 1559, 1564 n. 6 (11th Cir.1988), *cert. denied*, 490 U.S. 1006 (1989) ("If an overt act is necessary, then the indictment must charge and the evidence at trial must show that an overt act in furtherance of the conspiracy was made in the limitation period."); *United States v. Dolan*, 120 F.3d 856, 864 (8th Cir. 1997). The Tenth Circuit was unable to resolve the question, with the *en banc* court equally divided. *See, United States v. Stoner*, 98 F.3d 527, 531-38 (10th Cir. 1996), *aff'd*, 139 F.3d 1343 (10th Cir. 1998) (*en banc*).

The seminal case contrary to the Second Circuit viewpoint is *Davis*. As the Fifth Circuit there held, "for the purposes of the statute of limitations the overt acts alleged in the indictment and issued at trial mark the duration of the conspiracy." *Davis*, 533 F.2d at 929; *Accord, United States v. Loe*, 248 F.3d 449, 457 (5th Cir. 2001).

The decisions of this Court seem to support the *Davis* holding. In *Brown v. Elliot*, 225 U.S. 392, 401 (1912), the Court said, "where, during the existence of [a] conspiracy, there are successive overt acts, the period of limitations must be computed from the date, the last of them of which there is an appropriate allegation and proof." Similarly, in *United States v. McElvain*, 272 U.S. 633, 637 (1926), the Court upheld dismissal of the indictment on pretrial motion because "no act is alleged to have been done later than . . . three years prior to the indictment." *See also, Grunewald v. United States*, 353 U.S. 391, 406 n. 20 (1957) (rejecting government's theory that objective of conspiracy included "fixing" new tax fraud cases because "no overt act done to further the purpose of engaging in 'new' business was charged or proved to have occurred after October 25,

1951."); *Fiswick v. United States*, 329 U.S. 211, 216 (1946) ("The overt acts averted and proved . . . mark the duration, as well as the scope, of the conspiracy.")

The facts of the present case highlight the flaws and unfairness in the Second Circuit rule. The Petitioner was convicted on a substantive count on a theory different from that set forth in the indictment. Thus, the Second Circuit held on the first appeal that the indictment had been improperly constructively amended on that count.

This theory of prosecution – that the pharmaceutical drugs were contaminated – was, without any doubt, time barred.[7]

Yet, the Court let the conspiracy count stand,

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7. Milstein was indicted on the cusp of the 5 year statute of limitations, 18 U.S.C. §3282, in September 1998 for conduct that ended in 1993. *Milstein, supra*, 401 F.3d at 60. A new grand jury returned a superseding indictment in January 2000, when the Government had "recently discovered" evidence to support a contamination theory. This evidence was presented to the new grand jury, but there was no mention of it in the superseding indictment. *Id.* at 61.

concluding that, even though the invalid theory tainted the substantive count, the overt act of the invalid theory was a proper uncharged overt act. This overt act, however, would have been barred by the statute of limitations and could not be considered by the jury. The prejudice is manifest.

In short, the Second Circuit has decided important questions of conspiracy law in conflict with other circuits and the decisions of this Court. U.S. Sup. Ct. Rule 10(a). The writ should be granted to maintain consistency and uniformity in these issues.

CONCLUSION

For the foregoing reasons, the writ of certiorari should be granted.

Respectfully submitted,

JACOB LAUFER
Counsel of Record
65 BROADWAY
NEW YORK, NEW YORK 10006
(212) 422-8500
Attorney for Petitioner

New York, New York
June 12, 2007

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DECIDED MARCH 26, 2007

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Docket No. 06-1869-CR

UNITED STATES OF AMERICA,

Appellee,

v.

MOSHE MILSTEIN,

Defendant-Appellant.

Argued: Nov. 13, 2006.
Decided: March 26, 2007.

Before: SACK and WESLEY, Circuit Judges, and RAKOFF, District Judge.*

RAKOFF, District Judge.

Defendant-Appellant Moshe Milstein appeals from a judgment of the United States District Court for the Eastern District of New York (Dearie, J.) entered April 14, 2006, which, following our remand in *United States v. Milstein*,

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* The Honorable Jed S. Rakoff, United States District Judge for the Southern District of New York, sitting by designation.

401 F.3d 53 (2d Cir.2005) (per curiam), re-sentenced Milstein to a term of imprisonment of 20 months and restitution in the amount of approximately $3.5 million. Familiarity with the facts and procedural background of this case, as set forth in our prior opinion in *Milstein*, are here assumed.

Milstein was convicted by a jury of fraudulently distributing misbranded drugs in interstate commerce, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2) (Count Three); knowingly distributing wholesale prescription drugs in interstate commerce without a required state license, in violation of 21 U.S.C. §§ 331(t), 333(b)(1), and 353(e)(2)(A) (Count Four); knowingly distributing prescription drugs in violation of criminal trademark laws, 18 U.S.C. § 2320(a) (Count Two); distributing wholesale prescription drugs without providing the required history of transactions, in violation of 21 U.S.C. §§ 331(t), 333(a)(2), and 353(e)(1)(A) (Count Five); and conspiracy to commit the offenses specified in Counts Two, Three, and Four, in violation of 18 U.S.C. § 371 (Count One). The gist of the Government's case was that Milstein and others, taking advantage of the existence of less expensive (and less regulated) foreign versions of prescription drugs sold in the United States, purchased large quantities of three such drugs on the foreign market, repackaged them with counterfeit packaging so as to pass them off as their domestic counterparts, and sold them to doctors, pharmacists and pharmaceutical suppliers.

The original indictment, returned on September 16, 1998, alleged with respect to Count Three that Milstein and others had sold "re-packaged drugs as if they were the original product from the licensed manufacturers, thus distributing

misbranded drugs." *See Milstein*, 401 F.3d at 64. Some time after the original indictment was handed down, but before trial, tests performed by the Government and subsequently disclosed to the defense indicated that some of the repackaged drugs were contaminated with bacteria and endotoxins, even though they were labeled as "sterile." *Id.* This evidence was put before the grand jury, but neither the superseding indictment returned on January 26, 2000 nor the second superseding indictment returned after the trial began amended Count Three to add further allegations regarding this contamination. *Id.* Nevertheless, the Government presented evidence of the contamination at trial and the district judge charged the jury that it could convict on the misbranding count either on a false origin theory or on a contamination theory. *Id.*

On appeal, we held that the contamination theory amounted to a constructive amendment that did not "place Milstein on notice that the Government would . . . attempt to prove that the drugs were not sterile." *Id.* at 65. In all other challenged respects, however, we affirmed the conviction. *Id.* at 75. Accordingly, we vacated the conviction on Count Three only, and remanded for a retrial on Count Three if the Government wished to re-try that count, and, in any event, for re-sentencing.

On remand, the Government chose not to re-try Count Three, and the District Court re-sentenced Milstein. Although the District Court was in no way bound by its prior sentence, it chose to sentence Milstein to the same terms and conditions as the previous sentence, except, importantly, for the prison term, which was 20 months instead of the prior 48 months.

Appendix A

Following entry of judgment, defendant returned to this Court claiming to raise two new issues on appeal: (i) whether our conclusion that Count Three, the substantive misbranding count, had been constructively amended also required us to vacate Count One, the conspiracy count, which charged, *inter alia*, a conspiracy to commit the misbranding offense set out in Count Three; and (ii) whether the District Court erred in ordering Milstein to make restitution of approximately $3.5 million to the two companies whose trademarks he had misappropriated.[1]

The first issue, however, is far from "new" for the very same argument was expressly rejected in our prior decision. *See Milstein*, 401 F.3d at 66 ("We reject ... Milstein's contention that reversal of Count Three requires reversal of all counts .... [T]he contamination evidence was admissible in connection with Count One. ..."). As we there explained, the jury, as charged, was not presented with a constructive amendment of Count One and would have considered the contamination evidence, as far as the conspiracy count was concerned, as evidence of overt acts taken in furtherance of the conspiracy. *Id.* at 70-71. It is well settled that the "overt act element of a conspiracy charge may be satisfied by an overt act that is not specified in the indictment ... so long [as] there is no prejudice to the defendant." *United States v. Frank*, 156 F.3d 332, 337 (2d Cir.1998) (per curiam); *see*

1. In addition to these "new" issues, Milstein's brief also incorporated by reference several additional arguments made and rejected in *Milstein*, "solely to preserve them for possible Supreme Court review." To the extent those arguments are properly before us a second time, they are again rejected for the reasons stated in our prior opinion.

also United States v. Armone, 363 F.2d 385, 400 (2d Cir.1966). Since the contamination evidence was disclosed to the defense five months before trial, there was no prejudice in its introduction for this purpose. *See Milstein*, 401 F.3d at 71. Milstein's arguments to the contrary have gained no greater force in the 25 months since we previously rejected them.

The second issue, involving restitution, is, however, genuinely new, since it was not raised on the first appeal but was not thereby waived because Milstein was re-sentenced "de novo." *See United States v. Quintieri*, 306 F.3d 1217, 1225 (2d Cir.2002) *cert. denied*, 539 U.S. 902, 123 S.Ct. 2246, 156 L.Ed.2d 110 (2003).

As noted, the district court ordered Milstein to pay approximately $3.5 million in restitution to the two drug manufacturers whose trademarks he misappropriated. This figure reflected the sales that these two companies would have made if Milstein had actually purchased the products from them for distribution in the U.S. market. The district court based its authority to order restitution on the Victim and Witness Protection Act of 1982 ("VWPA"), 18 U.S.C. §§ 3663 *et seq.*, as it existed in 1993 (the time of the relevant offense conduct).[2] That statute expressly provided for restitution of "lost income" in cases involving bodily injury but was silent as to such recovery in cases of "damage to or loss or destruction of property." Specifically, section 3663(b) of the VWPA provided that:

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2. All citations herein to the VWPA are to this version of the statute.

Appendix A

(b) The order may require that such defendant-

(1) *in the case of an offense resulting in damage to or loss or destruction of property* of a victim of the offense—

(A) return the property to the owner of the property or someone designated by the owner; or

(B) if return of the property under subparagraph (A) is impossible, impractical, or inadequate, pay an amount equal to the greater of-

(i) the value of the property on the date of the damage, loss, or destruction, or

(ii) the value of the property on the date of sentencing, less the value (as of the date the property is returned) of any part of the property that is returned;

(2) *in the case of an offense resulting in bodily injury* to a victim—

(A) pay an amount equal to the cost of necessary medical and related professional services and devices relating to physical, psychiatric, and psychological care, including nonmedical care and treatment rendered in accordance with a method of healing recognized by the law of the place of treatment;

(B) pay an amount equal to the cost of necessary physical and occupational therapy and rehabilitation; and

(C) *reimburse the victim for income lost by such victim as a result of such offense;*

(3) in the case of an offense resulting in bodily injury [that] also results in the death of a victim, pay an amount equal to the cost of necessary funeral and related services; and

(4) in any case, if the victim (of if the victim is deceased, the victim's estate) consents, make restitution in services in lieu of money, or make restitution to a person or organization designated by the victim or the estate;

18 U.S.C. § 3663(b) (emphasis added).

The absence of any express reference to lost income in subsection(b)(1), when coupled with its express reference in (b)(2), led some courts to conclude that "unless and until [Congress] amends the statute to include lost income, courts may not order such restitution in property cases." *United States v. Mitchell*, 876 F.2d 1178, 1183 (5th Cir.1989); *see also United States v. Sharp*, 927 F.2d 170, 174 (4th Cir.1991) (citing *Mitchell* for the proposition that "Section 3663(b) does not provide for the recovery of lost profits."); *United States v. Dayea*, 73 F.3d 229, 231 (9th Cir.1995) ("The VWPA authorizes restitution for lost income in [only] two circumstances: where a victim has suffered bodily injury,

§ 3663(b)(2); or where the victim incurs expenses 'related to participation in the investigation or prosecution of the offense or attendance at proceedings related to the offense,' § 3663(b)(4)."). It appears, however, that such statements confuse the loss of income suffered by a victim of personal injury with the very different notion of lost profits as a measure of loss suffered by a victim of misappropriation of property.

Nothing in the text or legislative history of the VWPA precludes restitution for lost profits under section 3663(b)(1) where such losses amount to the "value of the property" the victim lost. Indeed, to hold to the contrary would thwart Congress's primary aim in enacting the VWPA, which was "to require 'the wrongdoer ... to the degree possible to restore the victim to his or her prior state of well-being.' " *United States v. Brown*, 744 F.2d 905, 910 n. 4 (2d Cir.1984)(quoting S.Rep. No. 97-532, at 30 (1982), *as reprinted in* 1982 U.S.C.C.A.N. 2515, 2536) (alteration in *Brown*). As the Sixth Circuit has noted, "including lost profits in the order of restitution [may be the] only way to assure the restoration of these victims to their prior state of well being." *United States v. Lively*, 20 F.3d 193, 202-03 (6th Cir.1994). *See also United States v. Rice*, 38 F.3d 1536, 1544 (9th Cir.1994)(upholding a VWPA restitution award based on the retail value of free samples fraudulently obtained because, if the defendant had "not obtained the free samples, [the victim] would have sold them, for their book-value. . . .").

Here, the District Court awarded lost sales as a form of restitution by distinguishing the instant case from cases like

Mitchell and *Sharp* on either of two alternative theories: *either* if the intangible property here involved was not within the scope of the "property" covered by subsection (b)(1), then the limitations of that subsection did not apply and restitution of lost sales would be available in accordance with other provisions of the statute; *or* if the intangible property here involved was within the scope of subsection (b)(1), what was being measured by the restitution of lost sales was not "lost income" but rather the "value of the property," as provided by that subsection.

We need not address the first of these theories, for we find that Milstein's infringement of his victims' trademark rights resulted in "damage to ... property" warranting the payment to the victim of "the value of the property on the date of the damage" pursuant to subsection (b)(1). It is well settled that trademarks are a form of property, *see Hamilton-Brown Shoe Co. v. Wolf Bros. & Co.*, 240 U.S. 251, 259, 36 S.Ct. 269, 60 L.Ed. 629 (1916)("The right to use a trademark is recognized as a kind of property ...."), and that intellectual or intangible property falls within the purview of criminal statutes designed to protect property. Thus, for example, in *Carpenter v. United States*, 484 U.S. 19, 25, 108 S.Ct. 316, 98 L.Ed.2d 275 (1987), the Supreme Court, having recently held that the mail and wire fraud statutes only protected property rights, *see McNally v. United States*, 483 U.S. 350, 360, 107 S.Ct. 2875, 97 L.Ed.2d 292 (1987), held that intangible property fell squarely within that protection.

On its face, subsection (b)(1) uses the term "property" without qualification. Furthermore, that subsection implicitly recognizes that not all property covered by the provision will

be tangible in nature, because it provides that if return of the property to the owner is "impossible, impractical, or inadequate"-terms neatly applicable to the misappropriation of intellectual property-restitution may be awarded in an amount equal to the "value of the property." The standard measure for determining the value to the victim of infringed trademarks is the victim's lost sales. *See* 15 U.S.C. § 1117(a)(1)-(2).[3] Here, the District Court, acting within its broad discretion to determine restitution, properly employed this measure, and, based on the evidence before it, made a reasonable estimate of the amount of lost sales.

Accordingly, the judgment of the district court is affirmed in all respects.

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3. While this is the measure in a civil case brought under the Lanham Act, there is no reason to believe it should be any less in a criminal case. Also, although it is true that, in a civil case, once the victim establishes the amount of lost sales, the burden shifts to the defendant to establish any deductions from that loss figure such as the manufacturer's costs, *see, e.g., Mishawaka Rubber & Woolen Mfg. Co. v. S.S. Kresge Co.*, 316 U.S. 203, 206-07, 62 S.Ct. 1022, 86 L.Ed. 1381 (1942), we need not determine here whether any such deductions would be available in a criminal case, for Milstein has not advanced any such claim on this appeal.

APPENDIX B — PER CURIAM OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DECIDED MARCH 10, 2005

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Docket Nos. 01-1499, 03-1414

UNITED STATES OF AMERICA,

Appellee,

v.

MOSHE MILSTEIN,

Defendant-Appellant.

Argued: May 24, 2004.
Decided: March 10, 2005.

Before: VAN GRAAFEILAND*, KEARSE, and WESLEY, Circuit Judges.

PER CURIAM:

Defendant-Appellant Moshe Milstein ("Milstein") appeals a judgment of the United States District Court for

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* The Honorable Ellsworth A. Van Graafeiland, who was a member of the panel, died on November 20, 2004. Prior to his death, he participated in the consideration and decision of this case and had initial responsibility for the opinion of the Court.

the Eastern District of New York (Dearie, *J.*), entered September 5, 2001, convicting him after a jury trial of distributing misbranded drugs in interstate commerce with fraudulent intent, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2) (Count Three); knowingly distributing wholesale prescription drugs in interstate commerce without a required state license, in violation of 21 U.S.C. §§ 331(t), 333(b)(1), and 353(e)(2)(A) (Count Four); knowingly distributing prescription drugs in violation of criminal trademark laws, 18 U.S.C. § 2320(a) (Count Two); distributing wholesale prescription drugs without providing the required history of transactions, in violation of 21 U.S.C. §§ 331(t), 333(a)(2), and 353(e)(1)(A) (Count Five); and conspiracy to commit the first three above-mentioned crimes, in violation of 18 U.S.C. § 371 (Count One). The District Court sentenced Milstein, under the Sentencing Guidelines ("Guidelines"), to 48 months in prison followed by three years of supervised release; fined him $25,000; and imposed a special assessment of $300. The Court also ordered Milstein to pay approximately $3.5 million in restitution to the drug companies that held the trademarks he had infringed.

On appeal, Milstein contends principally that the district court (a) erred in allowing the government to obtain a midtrial superseding indictment, (b) made erroneous evidentiary rulings, and (c) gave erroneous instructions to the jury. He also challenges the constitutionality of the federal statute requiring states to have a federally mandated scheme for licensing wholesale drug distributors engaged in interstate commerce. Finally, he contends that his sentence was impermissibly enhanced based on misinterpretations of the Guidelines and on facts not found by the jury, and that he is

entitled to be resentenced in any event because the Guidelines, treated as mandatory, are unconstitutional. For the reasons that follow, we vacate the judgment of conviction on Count Three; we remand for further proceedings with respect to that count and for resentencing; and we affirm the convictions on the other counts.

FACTUAL AND PROCEDURAL BACKGROUND

The evidence at trial, taken in the light most favorable to the government, revealed the following. Through several business entities, Milstein and others bought, repackaged, and sold foreign prescription drugs: Eldepryl, a medication used to treat Parkinson's disease, and the fertility drugs Pergonal and Metrodin.

The Food and Drug Administration ("the FDA") regulates the sale of prescription drugs, including Eldepryl, Pergonal, and Metrodin, in the United States. During the period of Milstein's drug sales, the only FDA-approved distributor of Eldepryl in the United States was Somerset Pharmaceuticals, Inc., of Tampa, Florida. The only FDA-approved distributor of Pergonal and Metrodin in the United States was Serono Labs USA, a subsidiary of Laboratories Serono, S.A., of Aubonne, Switzerland.

The Eldepryl, Pergonal, and Metrodin distributed in the United States by these companies were manufactured and packaged outside the United States in compliance with FDA standards. The companies also produced these drugs for distribution outside the United States with different packaging, and not necessarily in compliance with FDA standards.

Appendix B

Federal law imposes numerous requirements on the distribution of prescription drugs, of which three are relevant here. First, the law forbids distribution in interstate commerce of drugs that are misbranded. *See* 21 U.S.C. §§ 331(a), 333(a)(2), 352(a), (b), (i)(1), (j), 321(n). Second, the law forbids wholesale distribution of prescription drugs in interstate commerce without a state license. *See* 21 U.S.C. §§ 331(t), 333(b)(1), 353(e)(2)(A). Third, the law forbids wholesale distribution of prescription drugs without providing a history of transactions from the original manufacturer. *See* 21 U.S.C. §§ 331(t), 333(a)(2), 353(e)(1)(A). In addition, prescription drugs are subject to the general federal statutory prohibition of trafficking in counterfeit goods. *See* 18 U.S.C. § 2320.

The Government established at trial that Milstein and others purchased Eldepryl, Pergonal, and Metrodin produced for distribution outside the United States, stripped them of their original factory packaging, repackaged them with forged labels and packaging materials closely resembling those of drugs produced in accordance with FDA requirements for the U.S. market, and then fraudulently sold the drugs in the United States to doctors, pharmacists, and pharmaceutical wholesalers.

The principal witnesses at trial were Albert Silberberg, Alan Weisberger, and Alan Rosenblum, business associates of Milstein, who were not charged with any crimes in connection with this scheme. According to their testimony and other evidence, Milstein began distributing misbranded and counterfeit Pergonal in late 1991, and thereafter added Metrodin and Eldepryl. Milstein obtained foreign Pergonal,

Metrodin, and Eldepryl from one George Braun at prices lower than commanded by those drugs when prepared for the U.S. market.

Government lab analysis showed that the drugs Milstein distributed were not identical to the drugs prepared by their manufacturers for the U.S. market. The active ingredient in Milstein's Pergonal and Metrodin did not come from the same batch as the active ingredient in the drugs produced by the European manufacturer, Ares-Serono, for U.S. distribution. Moreover, some of the saline solution in the saline ampules packaged with Milstein's Pergonal and Metrodin contained quantities of bacteria and endotoxins, and therefore were not sterile. Milstein's Eldepryl also differed from the drug produced for the American market: his tablets were thicker, were off-white instead of white, and had dirt particles embedded in them. The Government alleged that Milstein was personally involved in repackaging the drugs to make it appear that they were produced for the U.S. market in accordance with FDA standards.

The Government also asserted that Milstein took substantial measures to hide his unlawful conduct from the Government. Specifically, the Government claimed that Milstein first sold his drugs through a company called WSE Distributors ("WSE"), and later formed a company called Gem Distributors ("Gem"), through which to sell the bulk of his drugs. Milstein needed a prescription drug wholesaler license to show to his customers. Rather than register and obtain a New York license to operate as a prescription drug wholesaler in New York (as he otherwise would be required to do since Gem did all of its business in New York), Milstein

registered WSE and later Gem as prescription drug wholesalers in New Jersey.

Actually, WSE's wholesaler application was filed in the name of Milstein's associate, Alan Weisberger. The Government also offered evidence that Milstein filed the wholesaler application for Gem in the name of Irving Goldstein. Milstein signed Goldstein's name, and five of Milstein's fingerprints were found on Gem's wholesaler filings. Milstein set up a fake supplier, Landys Ltd., in Hollywood, Florida, to make it appear that Gem had a legitimate supplier. After Milstein became aware of the investigation into his activities, he gave Silberberg fictitious Landys Ltd. invoices and a business card for Mark Landys, with instructions to show them to the FDA.

When an investigation of Milstein's activities appeared likely, Milstein transferred more than $400,000 in profits to his bank account in Israel by means of a complicated series of transactions, routed through accounts in Switzerland and Israel. When FDA agents eventually questioned Milstein regarding his drug sales, he falsely identified Goldstein as the owner of Gem, and Landys Ltd. as Gem's source for drugs. However, Goldstein's father testified that Goldstein was mentally unstable and not "well enough to be an owner of a chicken coop," and the Government's financial analysis showed that Goldstein received no profits from Gem.

In early September 1993, shortly before his interview with FDA agents, Albert Silberberg told Milstein he was worried about investigation rumors and wanted to stop distributing Milstein's drugs. Consequently, Milstein

arranged to sell directly to Silberberg's largest customer, Alan Rosenblum. Milstein's business associate Menachem Korall, using the name Mark Landys, then contacted Rosenblum, and the Pergonal and Metrodin sales continued. The continued illegal sales were accomplished through a new fictitious entity, M. Vase & Co., at a non-existent address. Rosenblum received deliveries of Pergonal and Metrodin on September 15, September 29, October 18, and December 6, 1993.

In September 1998, a grand jury returned an indictment charging Milstein, along with co-defendants Ethel Milstein and Menachem Korall, with criminal trademark infringement, distribution of misbranded drugs in interstate commerce, wholesale distribution of prescription drugs without the required state license, wholesale distribution of prescription drugs without providing required documentation of transaction history, and conspiracy to commit the first three of those crimes.

On January 26, 2000, a grand jury returned a superseding indictment directed to Milstein and one of his co-defendants, charging the five counts described above and adding a sixth count, alleging the filing of a false tax return. The Government also had recently discovered evidence that some of Milstein's prescription fertility drugs were contaminated with bacteria, and that evidence also was presented to the grand jury that returned the superseding indictment; but the Government did not have that portion of the indictment amended to reflect the newly-discovered evidence.

The superseding indictment, however, was imperfectly drafted. On March 8, 2000, immediately after the swearing in of the trial jury, Milstein moved for a judgment of acquittal on Count Four (wholesale distribution of prescription drugs without a state license) for failure to allege the jurisdictional element, *i.e.*, that the transactions took place in interstate commerce. In response, the Government sought leave to return to the grand jury to add an allegation of interstate commerce to the indictment. Meanwhile, the presentation of evidence at trial continued.

The Government received permission on March 17, 2000 to obtain an amendment of Count Four in order to meet the jurisdictional requirement. This task was accomplished in a novel manner. The District Court granted a midtrial "theoretical ... mistrial" on Count Four, prompted by the "manifest necessity" of Milstein's motion for acquittal based on Count Four's jurisdictional defect. (Trial Transcript ("Trial Tr.") at 1490.) The Government returned to the Grand Jury to secure an amendment of Count Four to allege the omitted jurisdictional element. In the meantime, the court allowed the trial to continue uninterrupted on all counts and announced that the evidence presented at the ongoing trial would be deemed presented in connection with the anticipated amended indictment. (*See id.* at 1491.)

On March 22, 2000, the Grand Jury returned a second superseding indictment, adding the phrase "in interstate commerce" in three places: paragraph 19 in Count Four (wholesale distribution of prescription drugs without a state license); paragraph 12(a) in Count One (charging conspiracy to commit the crime charged in Count Four); and paragraph

8 in the introductory section of the indictment that was incorporated by reference into Counts One through Five. Milstein was arraigned on the second superseding indictment on March 28, 2000, and entered a plea of not guilty without waiving his objection to the procedure. The Court then incorporated all of the prior trial evidence *nunc pro tunc* into the record of the trial on the second superceding indictment.

A jury convicted Milstein of Counts One through Five, and he entered a conditional guilty plea to the tax count, which had been severed from the counts tried. The District Court sentenced Milstein to 48 months in prison and three years' supervised release, fined him $25,000, and imposed a special assessment of $300. The District Court also ordered restitution to the victimized drug companies in the amount of approximately $3.5 million. Milstein has been released on bail pending this appeal.

DISCUSSION

I. *Criminal Trademark Infringement (Count Two)*

Milstein challenges his conviction on Count Two, intentionally trafficking in prescription drugs known to be counterfeit, in violation of criminal trademark laws ("Count Two"), 18 U.S.C. § 2320, asserting two errors: (1) that the District Court improperly instructed the jury as to what constitutes a "counterfeit mark"; and (2) that the District Court erroneously refused to permit the jury to consider a defense of laches.

Appendix B

A. *Jury Instruction on "Counterfeit Mark"*

A "counterfeit mark" is a "spurious mark . . . identical with, or substantively indistinguishable from," a registered trademark, "the use of which is likely to cause confusion, to cause mistake, or to deceive." 18 U.S.C. § 2320(e)(1)(A)(i-iii). At trial, Milstein conceded that he bought genuine prescription drugs made for foreign markets and then repackaged them for sale in the United States without the consent of the drugs' manufacturers. However, Milstein requested a jury instruction that a "spurious" mark is one used in connection with goods that are not "genuine" or are so altered as to lose their genuine character. The District Court refused, instructing the jury that "[a] counterfeit mark is a spurious mark or a mark that is not genuine," and "in order for the mark to be genuine, it must be placed there by the legitimate owner of the mark or with the owner's authorization." The Court further instructed, "[i]f you find that a good's production process includes the process of packaging, you may then find that the good does not bear a genuine mark if the good was repackaged using a trademark without authorization."

On appeal, Milstein contends that selling repackaged genuine goods is not a crime, and that "if the court's instruction were a correct statement of the law, any repackaging of genuine product would be a criminal trademark counterfeiting offense, even where, as here, there was no allegation that the packaging itself was trademarked." (Milstein brief on appeal at 62.) Milstein relies primarily on the Fifth Circuit's opinion in *United States v. Hanafy*, 302 F.3d 485, 486-89 (5th Cir.2002) (" *Hanafy* "), which held

that attaching a trademark to repackaged baby formula would not give rise to § 2320 liability. The Fifth Circuit suggested that, in the civil infringement context, Supreme Court precedent would require any repackaged good bearing a trademark to be "marked as having been repackaged." *Id.* at 488 (citing *Prestonettes, Inc. v. Coty*, 264 U.S. 359, 368-69, 44 S.Ct. 350, 68 L.Ed. 731 (1924)); *cf. Enesco Corp. v. Price/Costco Inc.*, 146 F.3d 1083, 1085-86 (9th Cir.1998). The *Hanafy* court declined to apply such a rule in the criminal context, however, reasoning that "Lanham Act precedent is of little value in a § 2320 case because the Lanham Act deals with civil liability." *Hanafy*, 302 F.3d at 489 (citing *United States v. Giles*, 213 F.3d 1247, 1250 (10th Cir.2000)). *But see United States v. Hon*, 904 F.2d 803, 805 (2d Cir.1990) ("There is no doubt that Congress wished to incorporate the Lanham Act's confusion requirement into 18 U.S.C. § 2320 and did so.").

Hanafy is readily distinguishable. The defendant in *Hanafy* resold cans of baby formula in trays that resembled trays used by manufacturers to sell the same product, bore the trademark holders' mark, and "contain[ed] no more information than that which [wa]s carried on the cans themselves." 302 F.3d at 486, 488. By contrast, Milstein "sold Eldepryl, Pergonal and Metrodin in forged packaging bearing false lot numbers." (Milstein brief on appeal at 9.) While the cans in *Hanafy* were "merely being repackaged, such that consumers could be sure of the goods' quality and source," *United States v. Farmer*, 370 F.3d 435, 441 n. 1 (4th Cir.2004) (citing *Hanafy*, 302 F.3d at 486), the drugs here were repackaged so that consumers would believe foreign versions of the drug were in fact domestic, FDA-approved versions (*see* Milstein brief on appeal at 60).

Milstein admits that the drugs "were repackaged in counterfeit packaging with phony lot numbers designed to resemble the authentic packaging approved by the [FDA]." (*Id.*) Although § 2320 has been read "effectively [to] exclude[ ] from the definition [of "counterfeit mark"] parallel imports, gray goods and production overruns," 4 *McCarthy on Trademarks* § 25:14 (2004), Milstein did more than resell parallel imports or gray goods. He obscured the fact that the drugs had been repackaged, and, with his package design, fraudulently conveyed that the foreign drugs had been manufactured as FDA-approved products. Moreover, he removed identifying codes from the repackaged goods. *Cf. John Paul Mitchell Systems v. Pete-N-Larry's Inc.*, 862 F.Supp. 1020, 1026-27 (W.D.N.Y.1994). In all the circumstances, given, *inter alia*, Milstein's knowing repackaging of the drugs without the trademark holders' authorizations, the jury permissibly convicted Milstein of violating § 2320(a).

B. *Jury Instruction on Laches Defense*

Milstein next contends that the District Court erred in failing to instruct the jury that laches was available as a defense to Count Two. Milstein cites 18 U.S.C. § 2320(c), which provides that "[a]ll defenses, affirmative defenses, and limitations on remedies that would be applicable in an action under the Lanham Act shall be applicable in a prosecution under this section." "It is well established that the equitable defense of laches may be applied to cases brought under the Lanham Act." *Conopco, Inc. v. Campbell Soup Co.*, 95 F.3d 187, 193 (2d Cir.1996) (citing 15 U.S.C. § 1069 ("In all inter partes proceedings equitable principles of laches . . . where

applicable may be considered and applied.")). Therefore, Milstein argues, the District Court erred in refusing to instruct the jury that the defense of laches, which requires that the defendant prove unreasonable delay resulting in prejudice, *see, e.g., King v. Innovation Books*, 976 F.2d 824, 832 (2d Cir.1992), was available to him. We disagree.

We begin by noting that, in the criminal context, the relevant statute of limitations, as well as the speedy trial safeguards of the Due Process Clause, *see, e.g., United States v. Lovasco*, 431 U.S. 783, 789-790, 97 S.Ct. 2044, 52 L.Ed.2d 752 (1977), serve to protect a defendant's interests against unreasonable delay. Further, it is well established that, as a general rule,

> [l]aches is not a defense to an action filed within the applicable statute of limitations, *United States v. Mack*, 295 U.S. 480, 489, 55 S.Ct. 813, 817, 79 L.Ed. 1559 (1935), nor is it available against the United States, *United States v. Summerlin*, 310 U.S. 414, 416, 60 S.Ct. 1019, 1020, 84 L.Ed. 1283 (1940).

United States v. RePass, 688 F.2d 154, 158 (2d Cir.1982). We have found no case applying a laches defense in the criminal context.

Of course, Congress could have provided that, in this context, such a defense would be available. Against the backdrop of these well-established principles, however, we decline to interpret the statutory scheme in that way. Section 1069 states that the laches defense may only be applied

"where applicable"; thus indicating that it may be applied in the criminal context at most where it would be applicable in an analogous civil context. Because laches may not be asserted against the United States in a civil matter, *see United States v. Angell*, 292 F.3d 333, 338 (2d Cir.2002) ("laches is not available against the federal government when it undertakes to enforce a public right or protect the public interest"), it seems that it is equally inapplicable against the Government in a criminal prosecution.

Further, the manifest purpose of 15 U.S.C. § 1069 is to encourage trademark holders timely to assert their rights against alleged infringers and to protect to some extent the alleged infringers' reliance interests. *See generally Conopco, Inc. v. Campbell Soup Co.*, 95 F.3d at 192-93. However, when or whether a trademark holder asserts its right against an alleged infringer is irrelevant to the Government's decision to begin a prosecution for criminal trademark infringement; criminal liability irrevocably attaches at the time of the willful infringement irrespective of the subsequent behavior of either the infringer or the trademark holder. Unlike other defenses to infringement, those contained in § 1069 do not go to the question of the alleged infringer's substantive liability, and therefore are not incorporated by § 2320(c).

Lastly, we note that construing the defense of laches to apply to prosecutions under § 2320 would lead to absurd results. The equitable doctrine of "unclean hands," it seems, would prevent its application in every prosecution under that section. As the Supreme Court has explained, "[t]he equitable powers of this court can never be exerted in behalf of one who has acted fraudulently, or who by deceit or any unfair

means has gained an advantage." *Bein v. Heath*, 47 U.S. (6 How.) 228, 246-47, 12 L.Ed. 416 (1848). Because "willful infringement" necessarily involves fraudulent acts, anyone convicted of it would be unable as a matter of law to benefit from a laches defense. Therefore we conclude that § 2320(c) does not evince a congressional intent to extend the equitable defense of laches to criminal prosecutions.

II. *Misbranding (Count Three): Constructive Amendment*

Milstein also was convicted of distributing misbranded drugs in interstate commerce with fraudulent intent, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2) (Count Three). The indictment on that count alleged that "[f]orgery or falsification of any part of the packaging material, including the instructional inserts, lot numbers or expiration dates, renders the drug misbranded under federal law," and that Milstein and others "regularly distributed [the modified drugs] that had been repackaged using forged materials." It further alleged that "[t]hey sold these re-packaged drugs as if they were the original product from the licensed manufacturers, thus distributing misbranded drugs."

Following Milstein's indictment, the Government claims to have learned that Milstein's drugs also were "contaminated" with bacteria and endotoxins. The Government contended that its contamination evidence was relevant to Count Three, charging Milstein with selling "misbranded" drugs, because saline ampules labeled "sterile" could be considered mislabeled if they were contaminated. On its return to the Grand Jury to obtain the second

superseding indictment adding the interstate commerce allegation to other counts, the Government also presented testimony regarding the contamination evidence to the grand jury. The Government did not, however, secure an amendment to Count Three of the indictment to allege that the drugs had been misbranded because they were supposedly sterile when they were not.

Nonetheless, at trial, the Government was allowed to present evidence of the contamination; and the court subsequently instructed the jury that it could find Milstein guilty of misbranding as alleged in Count Three if it found that "the labeling of the ampules of saline diluent suggested untruthfully that these ampules were sterile . . . when in fact they were a danger to health" (Trial Tr. 3870). Milstein argues that this instruction, allowing the jury to convict him of misbranding on the basis of the contamination evidence, constructively amended the indictment, leaving it uncertain whether he was convicted of the conduct alleged in the indictment. The Government contends that the generally framed indictment covered the specific theory that the drugs had been misbranded because they were labeled as if they were sterile when in fact they were not.

Although the cases dealing with claims of constructive amendment sometimes appear to reach divergent results, *see, e.g., Stirone v. United States*, 361 U.S. 212, 80 S.Ct. 270, 4 L.Ed.2d 252 (1960); *United States v. Zingaro*, 858 F.2d 94 (2d Cir.1988); *United States v. Salmonese*, 352 F.3d 608, 620-22 (2d Cir.2003) ("*Salmonese*"); *United States v. Danielson*, 199 F.3d 666, 669-71 (2d Cir.1999); *United States v. Patino*, 962 F.2d 263, 265-67 (2d Cir.1992), the

fundamental principle is clear. When the trial evidence or the jury charge operates to "broaden [ ] the possible bases for conviction from that which appeared in the indictment," the indictment has been constructively amended. *United States v. Miller*, 471 U.S. 130, 138, 105 S.Ct. 1811, 85 L.Ed.2d 99 (1985) (emphasis omitted). Constructive amendment is a *per se* violation of the Fifth Amendment. *United States v. Roshko*, 969 F.2d 1, 5-6 (2d Cir.1992). " 'To prevail on a constructive amendment claim, a defendant must demonstrate that either the proof at trial or the trial court's jury instructions so altered an essential element of the charge that, upon review, it is uncertain whether the defendant was convicted of conduct that was the subject of the grand jury's indictment.' " *Salmonese*, 352 F.3d at 620 (quoting *United States v. Frank*, 156 F.3d 332, 337 (2d Cir.1998)). There is no constructive amendment "where a generally framed indictment encompasses the specific legal theory or evidence used at trial." *Salmonese*, 352 F.3d at 620 (internal quotation marks omitted).

In the instant case, we are persuaded that the indictment, charging Milstein with misbranding due to his repackaging of the drugs, was constructively amended when the Government alleged that the drugs were misbranded because they were not sterile. At the time of Milstein's offenses, there were twenty different methods of misbranding, *see* 21 U.S.C. § 352(a)-(t) (1994) (describing ways in which one could misbrand drugs), *amended by*, *inter alia*, Food and Drug Administrative Modernization Act of 1997, Pub.L. No. 105-115, Title I, §§ 125, 126 (repealing 21 U.S.C. §§ 352(d), 352(k), 352(*l*)). Alleging, as the Government did in the second superseding indictment, that Milstein was charged

with misbranding because he "re-packaged drugs as if they were the original product from the licensed manufacturers" would not necessarily place Milstein on notice that the Government would also attempt to prove that the drugs were not sterile. The Government seemed to have recognized this when it presented the contamination evidence to the grand jury in the course of obtaining the amendment alleging the jurisdictional element. However, the Government neglected to have Count Three amended to include the contamination allegation. This is precisely the type of activity against which the Supreme Court cautioned in *Stirone:*

> The right to have the grand jury make the charge on its own judgment is a substantial right which cannot be taken away with or without court amendment. Here ... we cannot know whether the grand jury would have included in its indictment a charge that commerce in steel from a nonexistent steel mill had been interfered with. Yet because of *66 the court's admission of evidence and under its charge this might have been the basis upon which the trial jury convicted petitioner. If so, he was convicted on a charge the grand jury never made against him.

Stirone, 361 U.S. at 218-19, 80 S.Ct. 270.

Therefore, we vacate Milstein's conviction on Count Three and remand for a new trial on that count, should the Government wish to pursue the matter, *see, e.g., United States v. Wozniak*, 126 F.3d 105, 111 (2d Cir.1997); *United States v. Mollica*, 849 F.2d 723, 731 (2d Cir.1988).

We reject, however, Milstein's contention that reversal of Count Three requires reversal of all counts as a result of prejudicial spillover from what he characterizes as the "inflammatory" evidence of contamination on which the jury was instructed it could base its verdict on Count Three. As discussed in Part V below, the contamination evidence was admissible in connection with Count One, and thus was properly before the jury.

III. *Failure To Obtain a State License (Count Four)*

A. *Midtrial Superseding Indictment*

For two of the substantive counts against Milstein, (*i.e.*, Count Three alleging misbranding, and Count Four alleging the failure to have a state license), distribution in interstate commerce was an essential element of the offense. The indictment alleged such distribution in Count Three (*see* Superseding Indictment ¶ 17 (alleging that Milstein, with intent to defraud, "introduce[d] and deliver[ed] for *introduction into interstate commerce* drugs that were misbranded" (emphasis added))); but Count Four contained no similar allegation. When this omission was brought to the attention of the Government and the court shortly after the commencement of trial, the Government obtained a superseding indictment that added the phrase "in interstate commerce" to the licensing count.

In order to facilitate that addition, the District Court employed a somewhat unprecedented procedure. The Court declared a "theoretical ... mistrial" prompted by the "manifest necessity" of Milstein's motion for a judgment of

acquittal because the count was jurisdictionally defective. The Government returned to the Grand Jury to secure an amendment of the aforementioned count to allege the omitted jurisdictional element. And then the District Court incorporated all the prior trial evidence *nunc pro tunc*. The trial continued, with but a brief interruption for Milstein's arraignment on the new indictment. Milstein claims that this procedure violated his rights under the Double Jeopardy Clause and the statute of limitations. We are not persuaded.

1. *Double Jeopardy*

After jeopardy has attached, but before a verdict has been reached, the Double Jeopardy Clause of the Fifth Amendment does not prevent retrial where a mistrial "was required by 'manifest necessity.' " *Illinois v. Somerville*, 410 U.S. 458, 467-68, 93 S.Ct. 1066, 35 L.Ed.2d 425 (1973). The need to correct a jurisdictionally defective indictment presents one situation in which a mistrial is manifestly necessary. *See id.* at 468-69, 93 S.Ct. 1066. Therefore, at least where there is only minimal delay resulting from the mistrial and the Government is not thereby given the opportunity to strengthen its case, the Double Jeopardy Clause does not prevent retrial in such cases. *See id.* at 469, 93 S.Ct. 1066.

Milstein nevertheless contends that the Double Jeopardy Clause prohibits the procedure employed by the District Court in this case. However, given that the Government could have proceeded before a new jury on a new indictment, we cannot agree that allowing his trial to continue before the same jury violated the Double Jeopardy Clause. Indeed, doing so prevented a waste of all parties' "time, energy, and money,"

minimized almost completely any delay or potential prejudice to Milstein, and preserved his "right to have his trial completed by a particular tribunal"-the very values underlying the Double Jeopardy Clause. *See id.* at 468-70, 93 S.Ct. 1066 (emphasis omitted). Therefore, allowing the prosecution to continue upon the midtrial return of a superseding indictment was appropriate in this case.

Milstein argues that this Court's decision in *United States v. Dhinsa*, 243 F.3d 635 (2d Cir.2001), is to the contrary. In that case, however, the indictment was amended after the close of the Government's case, thus depriving the defense of the opportunity to cross-examine the Government's witnesses, thereby "increas[ing] the burden on [the defendant]'s defense." *Id.* at 668; *see also id.* at 664 (noting that its holding was "limited to the narrow circumstances" of that case). Here, by contrast, the new indictment was returned well before the close of the Government's case, the defense was on notice that the indictment would be superseded even earlier, and no change in defense strategy was required by the addition of the jurisdictional element to Count Four, especially given that distribution in interstate commerce was alleged as an element of Count Three. Therefore, *United States v. Dhinsa* is inapposite, as Milstein was in no way prejudiced by the substitution of the superseding indictment.

2. *Statute of Limitations*

Milstein also contends that the midtrial superseding indictment violated the statute of limitations, relying on *United States v. Gillespie*, 666 F.Supp. 1137 (N.D.Ill.1987).

However, *Gillespie* is not the law of this Circuit. *See United States v. Grady*, 544 F.2d 598 (2d Cir.1976) ("*Grady*"); *United States v. Drucker*, 453 F.Supp. 741 (S.D.N.Y.1978). "Once an indictment is brought, the statute of limitations is tolled as to the charges contained in that indictment." *Grady*, 544 F.2d at 601. Further,

> [w]henever an indictment . . . is dismissed for any reason after the period prescribed by the applicable statute of limitations has expired, a new indictment may be returned in the appropriate jurisdiction within six calendar months of the date of the dismissal of the indictment . . . , which new indictment shall not be barred by any statute of limitations.

18 U.S.C. § 3288. Thus, "a superseding indictment brought at any time while the first indictment is still validly pending," so long as it does not enlarge the first indictment's charges, "cannot be barred by the statute of limitations." *Grady*, 544 F.2d at 601-02.

In the instant case, the District Court, in allowing the Government an opportunity to secure an amendment to Count Four, did not immediately dismiss the first superseding indictment but rather continued the trial proceedings under that indictment. The second superseding indictment did not broaden the charges against Milstein but merely added a jurisdictional allegation, and the trial continued, without hiatus, under the second superseding indictment. Plainly, the second superseding indictment was not barred by the statute of limitations.

3. *Validity of Remaining Counts*

Milstein's contention that counts other than Count Four should be dismissed because of the alleged impropriety in the midtrial amendment to Count Four is moot in light of our above discussion. In any event, even had that midtrial amendment been impermissible, it would have provided no basis on which to disturb Milstein's conviction on the remaining counts. "[A]bsent a showing of prejudice, the erroneous amendment of one count does not destroy other counts of the indictment nor invalidate the judgment of conviction thereon." *United States v. Dhinsa*, 243 F.3d at 667 (internal quotation marks omitted). The Government's failure to allege the jurisdictional element in Count Four had no impact on any of the remaining counts, and Milstein has not shown any prejudice.

B. *Constitutional Challenge to Statute*

The Prescription Drug Marketing Act of 1987 ("PDMA") requires that any wholesaler of prescription drugs who would engage in interstate distribution be licensed by the state from which the drugs are to be shipped, under a state licensing scheme that complies with federal guidelines. *See* 21 U.S.C. § 353(e)(2)(A). Milstein was convicted of violating that provision, and now claims that the statute exceeds Congress's power under the Commerce Clause and violates the Tenth Amendment and the principles of federalism. He asserts that the statutory scheme has the same defects as the statutes struck down in *New York v. United States*, 505 U.S. 144, 112 S.Ct. 2408, 120 L.Ed.2d 120 (1992), *Printz v. United States*, 521 U.S. 898, 117 S.Ct. 2365, 138 L.Ed.2d 914 (1997), and

Board of Natural Resources v. Brown, 992 F.2d 937 (9th Cir.1993) ("*Brown*"). We disagree.

It is clear Congress may not "commandee[r] the legislative processes of the States by directly compelling them to enact and enforce a federal regulatory program." *New York*, 505 U.S. at 161, 112 S.Ct. 2408 (quoting *Hodel v. Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 288, 101 S.Ct. 2352, 69 L.Ed.2d 1 (1981)). "This is not to say that Congress lacks the ability to encourage a State to regulate in a particular way, or that Congress may not hold out incentives to the States as a method of influencing a State's policy choices." *New York*, 505 U.S. at 166, 112 S.Ct. 2408. "Congress may urge a State to adopt a legislative program consistent with federal interests," *id.*, and "it cannot be constitutionally determinative that the federal regulation is likely to move the States to act in a given way, or even to 'coerc[e] the States' into assuming a regulatory role by affecting their 'freedom to make decisions in areas of integral governmental functions,' " *Federal Energy Regulatory Commission v. Mississippi*, 456 U.S. 742, 766, 102 S.Ct. 2126, 72 L.Ed.2d 532 (1982) (quoting *Hodel*, 452 U.S. at 289, 101 S.Ct. 2352).

In *New York*, the Supreme Court struck down part of the Low-Level Radioactive Waste Policy Amendments Act of 1985, Pub.L. 99-240, 99 Stat. 1842, 42 U.S.C. § 2021b *et seq.*, which provided three types of "incentives" to encourage the states to regulate, in accordance with Congress's direction, the disposal of low-level radioactive waste generated within their borders. *New York*, 505 U.S. at 152, 112 S.Ct. 2408. One such "incentive" offered the states

the option, in lieu of timely compliance with the federal statute, of "taking title to and possession of . . . low level radioactive waste generated within their borders[, thereby] becoming liable for all damages waste generators suffer as a result of the States' failure to do so promptly." *New York*, 505 U.S. at 174-75, 112 S.Ct. 2408. That part of the statute "crossed the line distinguishing encouragement from coercion" and thus violated the Tenth Amendment. *Id.* at 175, 112 S.Ct. 2408.

In *Brown*, the Ninth Circuit held unconstitutional a portion of the Forest Resources Conservation and Shortage Relief Act, 16 U.S.C. §§ 620-620j. *See* 992 F.2d at 940. The statute at that time provided that "[e]ach State *shall determine* the species, grade, and geographic origin of unprocessed timber to be prohibited from export . . . *and shall administer* such prohibitions consistent with the intent of sections 620 to 620j of this title." 16 U.S.C. § 620c(d)(2) (emphases added). If the state decided not to administer the federal regulatory program, the state would have had to halt all timber sales, an alternative the Ninth Circuit held Congress had "no authority to command." *Brown*, 992 F.2d at 947.

The choice offered to the States by the PDMA is not equivalent to those in *New York* and *Brown*. Under the PDMA, a state is allowed to choose not to create a licensing framework pursuant to federal guidelines. The consequence is simply that a wholesale distributor may not distribute its prescription drugs from that state to another state. That consequence, though it may move a state to adopt the necessary licensing framework in order to encourage companies to do business in the state, does not transform

the provisions of the PDMA into a legislative scheme that is mandatory or coercive. Accordingly, we see no Tenth Amendment violation.

IV. *Failure To Provide History of Transactions (Count Five): Intent To Defraud*

Count Five charged Milstein with failing to provide his customers with the required pedigree information "with the intent to defraud and mislead." The "intent to defraud" element converts conduct that would otherwise be a misdemeanor into a felony. *See* 21 U.S.C. § 333(a)(1), (2). The District Court charged the jury that "intent to defraud" includes intent to defraud not only the wholesale distributors who made direct purchases from Milstein but also retail consumers and government agencies.

Milstein argues that it is doubtful that the government or consuming public ever can be a contemplated victim of a pedigree offense under 21 U.S.C. §§ 353(e)(1)(A), 333(a)(2). Milstein also asserts that he had no notice that he could have been convicted on the basis of evidence that he intended to defraud the purchasing public and government agencies. Therefore, he contends that the jury instruction violated his due process rights under the Fifth Amendment and the notice requirements of the Sixth Amendment.

Although there seems to be a split in authority, we believe that the Tenth Circuit's opinion in *United States v. Mitcheltree*, 940 F.2d 1329, 1347-50 (10th Cir.1991), is persuasive, holding that a defendant may be convicted on evidence that government agencies were the subject of the

intent to defraud. By misleading governmental agencies, and "thereby frustrating their efforts to protect the public," Milstein "indirectly misled and defrauded the public," thus contravening the "overriding congressional purpose [of] consumer protection" embodied in these provisions. *Id.* at 1348; *see also United States v. Bradshaw*, 840 F.2d 871, 874 (11th Cir.1988). *But see United States v. Haga*, 821 F.2d 1036, 1044 n. 17 (5th Cir.1987) (expressing doubt that government agencies could be victims of intent to defraud). Additionally, nothing in the language of the pedigree statute precludes the "intent to defraud" provision from applying to the purchasing public. Moreover, Milstein had adequate notice that the government agencies and the consuming public were possible subjects of his "intent to defraud."

The very nature of the fraud as alleged in the indictment implies an intent to defraud consumers. The indictment alleges that Milstein and others "sold these re-packaged drugs as if they were the original product from the licensed manufacturers," a scheme that on its face is designed to deceive all purchasers in the chain of distribution. Moreover, the documents provided by Milstein in discovery included records of his retail pharmacy customers showing patient prescriptions for Milstein's drugs.

Milstein received further notice of the Government's intent to prove that consumers were victims of the fraud when, in response to pre-trial motions, the Government described its contamination evidence, concluding that "[t]hese were powerful and potentially dangerous drugs distributed with a callous disregard for the health and well being of the end users." Similarly, in opposing Milstein's

pretrial motion to exclude the contamination evidence, the Government described the scheme as involving "counterfeit prescription drugs that were intended for injection by women having difficulty with conception and that were falsely labeled as sterile and safe for injection when, in fact, they were tainted with microorganisms that could cause infection." Though Milstein claims that these assertions were unscientific melodrama, they plainly placed him on notice that the consuming public was a potential subject of his "intent to defraud."

Likewise, the indictment placed Milstein on notice that the government charged him with intent to defraud government regulators. By charging the falsification of so-called "lot numbers," tools used by the FDA for further regulatory action, the indictment suggested a fraud that was reasonably understood to have been aimed at deceiving regulators. In addition, the Government's response to pretrial motions provided Milstein with a detailed account of the government's plan to prove his efforts to obstruct the FDA investigation, including his false statements to an FDA agent.

Therefore, the District Court correctly charged the jury that it could consider Milstein's intent to defraud customers and regulatory agencies as well as his direct purchasers.

V. *Conspiracy (Count One)*

A. *Constructive Amendment*

As discussed in Part II above, the introduction of "contamination evidence" constructively amended Count

Appendix B

Three of the Superseding Indictment because that count alleged misbranding through the use of forged packaging materials, and the District Court charged the jury that it could convict Milstein on that count if it found that he distributed goods that were contaminated rather than sterile. Milstein contends that the conspiracy count was similarly flawed because it charged Milstein with conspiring to, among other things, "introduce ... into interstate commerce drugs that were misbranded." We conclude, however, neither the introduction of the contamination evidence nor the district court's instruction pertinent to that evidence requires us to vacate Milstein's conviction on Count One.

It is a "well-established rule of this and other circuits that the overt act element of a conspiracy charge may be satisfied by an overt act that is not specified in the indictment, at least so long [as] there is no prejudice to the defendant." *United States v. Frank*, 156 F.3d 332, 337 (2d Cir.1998). Thus, even if the jury convicted Milstein on the conspiracy count based on evidence of an overt act not specified in the indictment (*e.g.*, an overt act involving drugs deemed misbranded because they are dangerous to health even when used as their labeling directed), the jury's reliance on that evidence would not require vacatur of Milstein's conspiracy conviction absent some indication that Milstein suffered prejudice as a result. Here, no indication of such prejudice is before us. Milstein had notice of the contamination evidence by August 1999, more than five months before his jury trial began.

Vacatur of a conviction may be warranted where instructions would permit the jury to "convict the defendant

of conspiracy without finding that he had any of the objectives alleged in the indictment." *United States v. Gallerani*, 68 F.3d 611, 618 (2d Cir.1995). Here, however, the jury instructions did not impermissibly broaden the objectives of the conspiracy as alleged in the indictment. The indictment alleged that Milstein and others conspired, *inter alia*, to "introduce and deliver for introduction into interstate commerce drugs that were misbranded." (Second Superseding Indictment ¶ 12.) This objective, as alleged, is sufficiently broad to encompass distribution not only of drugs that are misbranded because they have been repackaged in forged materials that misstate their origin, *see* 21 U.S.C. § 352(a), (b), (*i*)(1), but also of drugs that are misbranded because they are "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof," *id.* § 352(j).

The indictment also alleged, in the introductory section that was incorporated by reference into Counts One through Five, that Milstein and others "sold . . . re-packaged drugs as if they were the original product from the licensed manufacturers, *thus* distributing misbranded drugs" (Second Superseding Indictment ¶ 6) (emphasis added). Although as to the substantive offense charged in Count Three this allegation is sufficiently specific to restrict the government to proving an essential element of the offense (*i.e.*, that the drugs were misbranded) through a particular set of facts (*i.e.*, that the drugs were repackaged using forged materials that mischaracterized their origin), insofar as the conspiracy alleged in Count One is concerned, this allegation at most describes overt acts specified in the indictment. The

allegation does not, by its terms, address the objectives of the charged conspiracy, and we do not understand the allegation to narrow those objectives. *Cf. United States v. Salameh*, 152 F.3d 88, 146 (2d Cir.1998) (indictment's repeated references to the World Trade Center did not require the government to prove a specific conspiracy to bomb the World Trade Center where World Trade Center bombing was not listed as an object of the conspiracy, but merely as one of several overt acts alleged to have been committed in furtherance of the alleged conspiracy "to commit offenses against the United States"). Accordingly, we conclude that the introduction of the contamination evidence and the district court's instructions pertinent to that evidence did not constructively amend Count One of the indictment.

B. *Statute of Limitations*

Milstein also argues that his conspiracy conviction was barred by the five-year statute of limitations, *see* 18 U.S.C. § 3282. The original indictment against Milstein was returned on September 16, 1998; thus, for the conspiracy charge not to be time-barred, the government was required to allege and prove at least one overt act that occurred on or after September 16, 1993. *See, e. g., Salmonese*, 352 F.3d at 614. The indictment alleged, *inter alia*, that Milstein twice caused checks, totaling $47,350 and representing proceeds from the sale of prescription drugs, to be deposited in an account at the First International Bank of Israel in Switzerland (the "Swiss account") on September 17, 1993. Those two acts were the only overt acts within the limitations period that were alleged to have been committed by Milstein himself, and he argues that the evidence as to his commission of those

acts was insufficient to allow the jury to consider them. He also argues that those two acts were at most mere acts of concealment and therefore that they cannot serve to extend the life of the conspiracy. These contentions are meritless.

To begin with, Milstein's premise, *i.e.*, that the conspiracy charge against him would be time-barred unless the government could prove that Milstein himself committed overt acts within the limitations period, is legally flawed. Foreseeable acts of one co-conspirator in furtherance of the conspiracy are attributable to all co-conspirators. *See, e.g., United States v. Ben Zvi*, 242 F.3d 89, 97 (2d Cir.2001) (statute of limitations depends on timely overt act by either the defendant or a coconspirator). There is no evidence that Milstein had ceased to be a co-conspirator. *See, e.g., United States v. James*, 609 F.2d 36, 41 (2d Cir.1979) (an alleged withdrawal from a conspiracy prior to a given point in time is an affirmative defense that the defendant has the burden of proving by a preponderance of the evidence). Given that the indictment alleged 10 other overt acts by co-conspirators within the five years preceding the indictment, the conspiracy offense charged against Milstein in Count One was not time-barred.

Further, there was ample evidence at trial that the Swiss account was linked to Milstein and his co-conspirators and that the two checks, which were payable to Milstein's company, were deposited on September 17, 1993. Therefore, the evidence was sufficient to support an inference that Milstein caused the deposit of those two checks into the Swiss account.

Finally, although it is established that "mere overt acts of concealment" of the commission of the crime would not extend the life of a conspiracy after its "central criminal purposes" had been attained, *Grunewald v. United States*, 353 U.S. 391, 401-2, 77 S.Ct. 963, 1 L.Ed.2d 931 (1957), we have "consistently ruled that where a conspiracy's purpose is economic enrichment, the jointly undertaken scheme continues through the conspirators' receipt of their anticipated economic benefits." *Salmonese*, 352 F.3d at 615 (internal quotation marks omitted). Thus, efforts to secrete or launder moneys gained from a scheme for monetary gain, and to safeguard them from discovery or recovery, are to be considered acts in furtherance of the conspiracy, rather than mere acts of concealment of the commission of crime. In this case, the checks-payable to Milstein's company-were deposited in the Swiss account, an account that the Government showed was connected to the conspiracy through a series of bank transfers, including prior transfers from the Swiss account to an account maintained by Milstein in Israel, via the account of one of Milstein's co-conspirators. The jury was entitled to infer that the September 17 deposits were part of the conspirators' efforts to reap-and keep-economic gains from their conspiracy and, thus, that those deposits were more than mere acts of concealment of the crime.

VI. *Excluded Co-Conspirator Statements*

Milstein also contends that the District Court erroneously excluded from evidence a tape-recorded conversation, proffered by Milstein, between Rosenblum and Silberberg. Describing Rosenblum and Silberberg (who were not indicted) as his co-conspirators, Milstein claims the tape

should have been admitted into evidence under Federal Rule of Evidence 801(d)(2)(E) as an admission of a co-conspirator. (*See* Milstein brief on appeal at 67-70.) His reliance on that Rule is misplaced.

> "[A] statement by a coconspirator of a party during the course and in furtherance of the conspiracy" is one type of "[a]dmission by party-opponent" defined as nonhearsay, but only if "offered against" the party. Fed.R.Evid. 801(d)(2)(E). The statement of a conspirator, offered for its truth by a co-conspirator, is not within this Rule. *See United States v. Kapp*, 781 F.2d 1008, 1014 (3d Cir.1986).

Milstein's reliance on *United States v. Tin Yat Chin*, 371 F.3d 31 (2d Cir.2004), for the proposition that "it should make no difference which party to the litigation the statement is used against" (Milstein reply brief on appeal at 32) is misplaced. That case involved a question of whether the proffered evidence had been sufficiently authenticated, not whether it came within the hearsay rule. Out-of-court statements by the party offering the statements and out-of-court statements by co-conspirators of the party offering the statements, when offered for their truth, remain hearsay and are not admissible unless they fit within an exception to the hearsay rule. No applicable exception has been called to our attention. We conclude that the District Court properly excluded the co-conspirator tape proffered by Milstein.

Appendix B

VII. *Sentencing*

Finally, Milstein contends that the district court, in calculating his sentence under the 1994 Sentencing Guidelines, erred by enhancing his offense level pursuant to U.S.S.G. § 3A1.1 on account of the vulnerability of his victims and § 2F1.1(b)(1) for the amount of loss caused by his offense. He also contends that application of the Guidelines on a mandatory basis is unconstitutional.

The latter contention has merit in light of the Supreme Court's recent decision in *United States v. Booker*, 543 U.S. 220, 125 S.Ct. 738, 160 L.Ed.2d 621 (2005) ("*Booker/Fanfan*"), holding that, to eliminate Sixth Amendment error, the Guidelines must be deemed advisory rather than mandatory. We note, however, that, because we are vacating one of the counts of conviction, we would ordinarily remand for further proceedings and resentencing even without *Booker/Fanfan*, *see*, *e.g.*, *United States v. Laljie*, 184 F.3d 180 (2d Cir.1999); *see generally United States v. Quintieri*, 306 F.3d 1217, 1227-28 (2d Cir.2002) ("[a] district court's sentence is based on the constellation of offenses for which the defendant was convicted," and "[w]hen the conviction on one or more charges is overturned on appeal . . . , the constellation of offenses of conviction has been changed"), and we will follow that course in this case.

As discussed in this Court's post- *Booker/Fanfan* decision in *United States v. Crosby*, 397 F.3d 103 (2d Cir.2005), although the Guidelines are no longer mandatory, a sentencing court is nonetheless required to consider the relevant guidelines provisions in determining a reasonable

sentence. Accordingly, for the guidance of the district court's sentencing considerations on remand, we address Milstein's challenges on this appeal to the district court's interpretation of the vulnerable-victim and loss guidelines.

A. *Vulnerable Victim*

A District Court may enhance the sentence of a defendant if the defendant "knew or should have known that a victim of the offense was unusually vulnerable due to age, physical or mental condition, or that a victim was otherwise particularly susceptible to the criminal conduct." U.S.S.G. § 3A1.1. Application Note 1 to this guideline provides that this "adjustment would apply, for example, in a fraud case where the defendant marketed an ineffective cancer cure . . . ."

In this case, Milstein chose to distribute counterfeit and misbranded drugs to doctors, pharmacists, and pharmaceutical wholesalers, knowing that those customers would distribute the drugs to women with fertility problems and to Parkinson's disease patients. We see no error in the District Court's view that victims with fertility problems and/or with Parkinson's disease are particularly vulnerable in this context.

B. *Loss Calculation*

Under the Guidelines, a defendant's sentence in a case involving fraud is to be calculated in part with reference to the amount of loss inflicted as a result of the offense. *See* U.S.S.G. § 2F1.1(b)(1). Loss for these purposes includes

"the actual, probable, or intended loss to victims of the fraud." *United States v. Chatterji*, 46 F.3d 1336, 1340 (4th Cir.1995); *see, e.g., United States v. Brach*, 942 F.2d 141, 143 (2d Cir.1991). Although Milstein contends that the District Court should have not have calculated the loss caused by his offenses without giving him credit for the value of the products consumers received, citing *United States v. Maurello*, 76 F.3d 1304 (3d Cir.1996) (services of disbarred lawyer have some value), and *United States v. Prigmore*, No. CR. 93-10276-JLT, 1996 WL 464030 (D. Mass. Aug 7, 1996) (heart catheter lacking FDA approval has some value), no such credit was required here. The district court may permissibly reason that contaminated medicine is worthless to the consumer. *See, e.g., United States v. Gonzalez-Alvarez*, 277 F.3d 73, 77-80 (1st Cir.2002) (adulterated milk, which "cannot be sold lawfully[,] ... has a value of zero"); *see also United States v. Bhutani*, 266 F.3d 661, 669-70 (7th Cir.2001) (where "consumers bought drugs under the false belief that they were in full compliance with the law," district court may appropriately determine that "the defendant's gain is the appropriate measure of th[eir] loss").

In the present case, the District Court found that the "loss" suffered by the victims was $4.1 million, based on the sales figures for the prescription drugs that Milstein and his co-conspirators sold during the period of 1991-93. This determination properly reflected the Guidelines as they were applicable to Milstein, and as they were later clarified. The clarification, adopted with a reformulation of the fraud guidelines in 2001, states as follows:

Appendix B

> In a case involving a scheme in which (I) services were fraudulently rendered to the victim by persons falsely posing as licensed professionals; (II) goods were falsely represented as approved by a governmental regulatory agency; or (III) goods for which regulatory approval by a government agency was required but not obtained, or was obtained by fraud, loss shall include the amount paid for the property, services or goods transferred, rendered, or misrepresented, with no credit provided for the value of those items or services.

U.S.S.G. § 2B1.1, Application Note 2(F)(v)(2001). Although this clarification may not be directly applicable to the present case, as it was adopted after Milstein was sentenced, it clarified the law as it stood when Milstein was sentenced. We see no error in the district court's interpretation of the guidelines concerning the calculation of loss.

CONCLUSION

We have considered all of Milstein's contentions on this appeal and, except as indicated above, have found no basis for reversal. We AFFIRM the convictions on Counts One, Two, Four, and Five. We VACATE the judgment of conviction on Count Three, and we REMAND to the District Court for further proceedings on Count Three, should the Government decide to reprosecute, and for resentencing in accordance with the foregoing.

APPENDIX C — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK DATED MARCH 3, 2000

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

No. CR96-899(RJD).

March 3, 2000.

UNITED STATES OF AMERICA

v.

Moshe MILSTEIN, et al.,

Defendants.

MEMORANDUM AND ORDER

DEARIE, J.

The Court issues the following rulings in response to the defense pre-trial motions.

Constitutionality of 21 U.S.C. § 353(e)(2)(A)

The motion to dismiss Count Four of the original indictment on the grounds that section 353(e)(2)(A) of Title 21 is unconstitutional is denied. The statute in question does not mandate state legislatures to do anything. The regulations

issued in accordance with the authority of section 353(e)(2)(B) do not evidence an intrusion into state sovereignty, but merely, as designed, provide for very basic common sense requirements as a condition to compliance with federal law. Overall, the largely deferential statutory and regulatory scheme does not come close to the congressional excesses struck down in *New York v. United States*, 505 U.S. 144 (1992) and *Printz v. United States*, 117 S.Ct. 2365 (1997).

Counterfeit vs. Grey Market

The defense seeks the dismissal of Count Two on the ground that the evidence will show that the drugs are not counterfeit within the meaning of section 2320(e)(1). The allegations, if proven, establish the sort of egregious conduct that falls far outside the grey goods or parallel imports exception. Accepting for the moment the government's proffer and those facts that appear to be essentially uncontested, the total products were not what they appeared to be. Even putting aside evidence of adulteration (which the defense insists is irrelevant to the issue of counterfeiting-not without some irony), evidence of false packaging, drug processing outside the usual FDA controls and fake lot numbers, if credited by the factfinders, will satisfy the statutory definition. At this point in the proceedings at least, the charge is properly alleged and the evidence will be presented to the jury.

Appendix C

Laches

The defense counsel argue that laches bars the prosecution of Count Two. Laches is adefense to an equitable claim, and its availability is governed by Title 15 of the United States Code, section 1115. This is a criminal case, and the timeliness of the prosecution is determined by the five year statute of limitations. In any event, although the government might have been more forthcoming in explaining the delay in bringing formal charges the Court is satisfied that the international aspects of the case and the attendant investigational difficulties presented in this and related investigations give a clear indication as to why the case proceeded at its relatively slow pace.

The "documentation" requirement of 21 U.S.C. § 353(e)(1)(A)

The motion to dismiss Count Five is denied. The text of the count accurately tracks the language of section 353(e)(1)(A) and is therefore properly charged. The parenthetical, "Distribution of Prescription Drugs Without Required Documentation" will be deleted from the copy of the redacted Indictment furnished to the jury.

The Court appreciates that the issue presented will likely mature and require closer attention following the close of the evidence in preparation of the Charge to the jury.

Appendix C

Counts 2, 3, and 5 are not duplicitous

The defense seeks the dismissal of Counts 2, 3, and 5 on the grounds that each charges multiple acts or offenses in violation of Rule 8 of the Federal Rules of Criminal Procedure.

It is well-established in this and other Circuits that "acts that could be charged as separate counts of an indictment may instead be charged in a single count if those acts could be characterized as part of a single scheme." *See United States v. Tutino*, 883 F.2d 1125, 1141 (2d Cir.1989). This charging latitude is not indigenous or limited to allegations of mail and wire fraud. The offense charged in the relevant counts alleged an ongoing activity for a period of at least a year and a half. The anticipated evidence, according to the government's proffer, supports the characterization of continuing criminal activity.

The defense concerns about the statute of limitations and unanimity will be addressed in the Court's instructions to the jury. The motion to dismiss is denied. Similarly, the issue of multiple conspiracies will be addressed, if appropriate, following the evidentiary phase of the trial.

Motions in Limine

The Court will address with counsel the outstanding motions in limine following the evidentiary hearing on the defendant **Moshe Milstein's** motion to suppress.

Appendix C

Motion to Quash Subpoena to Scientific Lie Detection, Inc.

In anticipation of the government's opposition papers to the motion to quash this subpoena, the Court requests that the assigned Assistant United States Attorney provide information as to whether the subpoena was served with the approval of the United States Attorney and the appropriate officials of the Department of Justice.

The Trial

Jury selection will be begin promptly at 10 A.M. on Monday, March 6, 2000. The suppression hearing will follow. Counsel are to report to the courtroom at 9:30.

Requests to Charge are to be filed no later than Wednesday, March 15th. The Court contemplates a four day trial schedule assuming adequate progress is made. A specific schedule will be prepared after consultation with all counsel. Following the close of the evidence, the Court will sit five days.

SO ORDERED.